

APPLICANT(S): Adrian PAZ
SERIAL NO.: 10/563,229
FILED: January 3, 2006
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REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection which were raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

It is respectfully submitted that no new matter was introduced via the amendments.

Status of Claims

Claims 1-28, 33-35 and 38-40 are canceled. Claims 29-32, 36-37, and 44-48 are currently amended. Claims 41-43 are withdrawn. New claim 49 is added.

Claim 29 is amended to read:

"A surgery-assisting retraction device (SARD) useful in minimally invasive surgeries for retraction of an organ within the abdominal cavity of the human body, said SARD comprising:

- a. at least one first anchoring means adapted to be reversibly attached to an anchoring point on the internal abdominal wall; and,*
- b. at least one second anchoring means being interconnected to said at least one first anchoring means via coupling means; said second anchoring means*

adapted to be reversibly attached to said organ within said abdominal cavity, such that when said SARD is activated, the same retracts said organ with respect to said anchoring point;

wherein said anchoring point is located on the internal surface of said abdominal wall, such that creation of an opening at the location of said anchoring point for said retraction is prevented"

Support for the phrase "**anchoring point**" is found, inter alia, in the 'MODES FOR CARRYING OUT THE INVENTION' paragraph [0081]: "*Fig. 1 illustrates a virtual anchoring point device with internal magnet, to attach to an abdominal wall 11 of the abdominal cavity 12, inside the human body*".

Support for the phrase "**coupling means**" is found, inter alia, in the 'MODES FOR CARRYING OUT THE INVENTION' paragraph [0091]: "*To the virtual port device is attached, through a string, a tissue grasping means.*"; and, in the 'MODES FOR CARRYING OUT THE INVENTION' paragraph [0094]: "*Alternatively, instead of a string, a rod may be attached to the anchoring means serving to push away the tissue from the anchoring device. Also, a combination of pulling and pushing retractor means may be used.*"

Support for the phrase "**creation of an opening in said body for the attachment of said at least one first anchoring means to said anchoring point, is prevented**" is found, inter alia, in the 'MODES FOR CARRYING OUT THE INVENTION' paragraph [0080]: "*The device is initially introduced through an opening in the cavity wall and then attached to some location on the undersurface of the cavity wall, or to various tissues within a cavity, by some non-invasive attachment means.*", and in the 'DISCLOSURE OF THE INVENTION' paragraph [0027]: "*The device includes means allowing it to be moved from one position to another and reattached to the undersurface of the abdominal*

wall, or to various tissues within a cavity, without creating any additional openings in the cavity wall."

Claim 31 has been amended to read:

"The SARD according to claim 29, wherein said SARD is moveable in any predetermined direction from one anchoring point to another anchoring point on said abdominal wall without creating any additional openings at the location of said anchoring points."

Support for the phrase " ...said SARD is moveable in any predetermined direction from one anchoring point to another anchoring point on said abdominal wall... " is found, inter alia, in the 'DISCLOSURE OF THE INVENTION' paragraph [0027]: *" The device includes means allowing it to be moved from one position to another and reattached to the undersurface of the abdominal wall, or to various tissues within a cavity, without creating any additional openings in the cavity wall."*

New claim 49 has been added. Claim 49 now reads:

"The SARD according to claim 29, wherein said coupling means is selected from the group consisting of: a string, a tissue attachment means, a rod, a magnetic field, or any combination thereof."

Support for the phrase "a string, a tissue retractor means, a rod,..." is found, inter alia, in the 'MODES FOR CARRYING OUT THE INVENTION' paragraph [0094]: *"Alternatively, instead of a string, a rod may be attached to the anchoring means serving to push away the tissue from the anchoring device. Also, a combination of pulling and pushing retractor means may be used."*

CLAIM REJECTIONS

35 U.S.C. §112 Rejections

Claims 29-32, 36, 37, and 44-48 of the present application, are rejected to by the examiner under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and the enablement requirements.

With regards to said claims, the term 'external forces' has been deleted.

Claims 31 of the present application, is rejected to by the examiner under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claim 31, said claim has been amended and the phrase "the under surface" has been deleted from said claim.

35 U.S.C. §102 Rejections

Claims 29-32, 37, and 44-48 of the present invention were rejected to by the examiner under 35 U.S.C. 102(e) as being anticipated by Lonky, US patent No. 6,641,575 (refers hereinafter as '**575**').

The applicant maintains that the device of the present invention differs from that of Lonky.

The present invention provides a surgery-assisting retraction device (SARD) for use in minimally invasive surgeries within a cavity of the human body. The device comprises at least one first anchoring means and at least one second anchoring means.

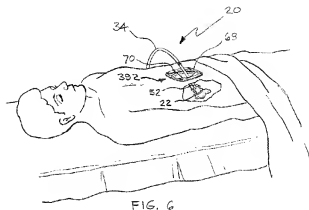
The first anchoring means of the SARD is attached to an anchoring point, and the second anchoring means of the SARD is attached to an organ within the cavity.

The novel and non-obvious effect which is provided by the present invention is that the anchoring point is located at an internal surface of the abdominal wall. The main advantage provided by the present invention is that the location of the anchoring point at an internal surface of the abdominal wall within said cavity prevents the creation of an additional opening in the patient's body at the anchoring point.

Patent '575 discloses a surgical vacuum device which includes a vacuum cup attachable to an organ. This device is provided with an ability to be retracted without the need of a surgical assistant. Once an appropriate retraction force is applied to the cup, a tensioning structure (the 'coupling means' in the present invention), for example, a cord, a hook, or the vacuum tube is secured in a specific position.

According to patent '575 (col. 2, lines 62-65), the cup which is connected to the organ may be retracted via the tensioning structure by one the following means:

- (i) Retraction to an external framework such as a frame anchored to or adjacent to the surgical field. This retraction is clearly illustrated in FIG. 6 of patent '575.



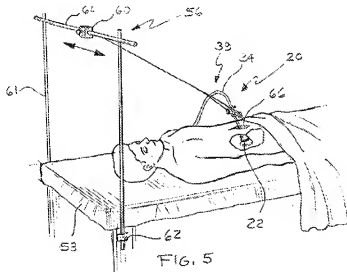
Col. 5, lines 34-40 of patent '575 discloses how this retraction is performed:

"Alternately, the device 20 may be coupled to a conventional self-retaining retractor 68 as illustrated in FIG. 6. While it may be coupled by any appropriate method, the traction cord 52 may be hooked on a lock nut 70 of the retractor 68 .";

Such a retraction is an preformed as an open surgery and does not fall within the definition of the new amended claim 29 which reads an internal anchoring point, i.e., on the internal abdominal wall without the creation of an additional opening.

Furthermore, such a retraction suffers from limitations when the retracted organ and the incision through which the vacuum tube is inserted are relatively far from each other. Such a situation occurs frequently, especially in laparoscopic procedures. For example, this method of retraction cannot provide a local retraction of the organ in which the retracted organ will face predetermined direction in any desired angle within the cavity. In patent '575 the retraction method of the organ is enabled only to a specific direction, which is the direction of the main incision. Hence, this solution of retraction is only partial.

- (ii) Retraction to a frame which is coupled to the table. This retraction is clearly illustrated in FIG. 5 of patent '575 as follows:



Col. 5, lines 25-27 of patent '575 discloses the performance of such retraction:

"For example, the cord 52 may be coupled to a frame 56 extending above the operating table 58, as illustrated in FIG. 5."

This kind of retraction also suffers from limitations which are similar to those of the first retraction technique.

(iii) Retraction to a self retaining retractor at the incision. Such a retraction is clearly illustrated in FIG. 7 of patent '575 as follows:

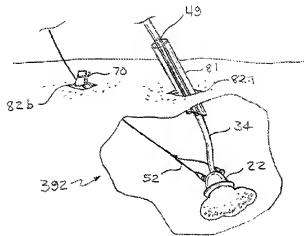


FIG. 7

Col. 5, lines 38-40 of patent '575 discloses said retraction:

"Similarly, during laparoscopic procedures, the cord 52 might be clipped via an appropriate clip 70 directly to the patient's skin, as illustrated in FIG. 7."

Patent '575 clearly states that the cord 52 or the clip 70 is attached to the patient's skin. It is emphasized that the skin is by no means equivalent to the internal abdominal wall or any other internal tissue. Furthermore, it should be pointed out that in order to implement the device of patent '575 in a single port operation, the physician will literally have to drill from the internal cavity upwardly towards the outer surface of the skin in order to couple the clip 70 to the skin. Such a drilling is neither simple, minor procedure nor is it desired for both the physician (namely due to the elongation in operational time) or the patient (namely due to the elongation in recovery time).

Furthermore, patent '575 states that *an additional incision* has to be made in order to retract the organ:

"It will be appreciated that in this particular application, the cord 52 or other tether is applied through one incision, while the suction hose 34 extends through another incision"

(see col. 5, lines 40-44)

A creation of an additional incision is a critical limitation in the field of laparoscopic surgeries. In laparoscopy it is well known that **a single port procedure is preferred**. Each incision in the body of the patient, leaves scars, and requires recovery.

Moreover, in creation of an additional incision, there is always a risk of infections. Therefore, creation of an additional incision in the body of the patient should be prevented if it possible.

A main distinction between the device of the present invention and the device of patent '575 lies in the fact the device of the present invention retracts the organ **without** creating an additional incision at the location of the anchoring point, and without pulling the retracted organ to a direction which might be unwanted (namely, the direction of the main incision through which the device is inserted).

Another distinction between the present invention and patent '575 is that the present invention provides an ability to change the location of the anchoring point and thus to change the direction of the retraction during the procedure **without the need to create any additional openings at the abdominal wall**. By using the device of patent '575, each time the surgeon changes the direction of the retraction, an opening at the abdominal wall has to be created. This creation of an additional opening is prevented when the device of the present invention is used. By using the device of the present invention, the surgeon has the freedom the change the direction of the retraction and the

location of the anchoring point as many times as needed, without injuring the patient's body.

The following figure of a specific embodiment of the present invention which clearly illustrates that no additional openings are made in the body, and no retraction towards the direction an external frame is performed:

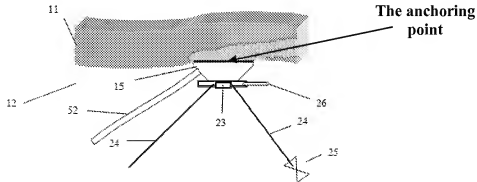


Fig. 3

Patent '575 does not describe or even suggest that the device may be anchored to an anchoring point which is located at an internal surface of the abdominal wall, and without making additional incisions in the patient's body.

Yet more, it should also be mentioned that while patent '575 discloses only type of means (connection to a clip) for the connection of first anchoring means to the anchoring point, the present invention discloses much wider variety of means which may be used for this purpose. According to the present invention, the first anchoring means might be connected to the anchoring point via attachment means selected from: vacuum cups, magnetic means, mechanical means, adhesive means, etc. The present invention also provides examples for the use of these various attachment means.

While the devices of patent '575 and the present invention have one end attached to an organ and another end which is retracted to an anchoring point, as presented above, major key differences exists:

- (a) the first anchoring means; patent '575 attaches the first anchoring means to an anchoring point which is external to the body, or to a frame of the main incision, or at another incision. On the contrary, in the present invention, the first anchoring means itself is attached to an internal tissue of the abdominal wall in order to provide retraction of the organ.
- (b) the ability the change the direction of the retraction without the need the create additional openings at the abdominal wall; By using the various attachment means provided by the device of the present invention, for the attachment of the first anchoring means to the abdominal wall, the surgeon is able the change the direction of the retraction and the location of the anchoring point without creating additional openings at the abdominal wall. This ability is not disclosed or even suggested by patent '575.

Favorable action on this amendment is courteously solicited.

35 U.S.C. §103 Rejections

Claim 36 of the present invention were rejected to by the examiner under 35 U.S.C. 103(a) as being unpatentable over Lonky, US patent No. 6,641,575 (refers hereinafter as '575).

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It is respectfully submitted that in the light of the arguments above, claim 36 which is dependant on newly amended claim 29, which is now novel and non-obvious over patent '575.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, or if there are any further issues yet to be resolved to advance the prosecution of this application to allowance, the Examiner is requested to contact the undersigned at the telephone number below.

No fees are believed due. However, the United States Patent and Trademark Office is hereby authorized to charge Deposit Account No. 501380 any fees that may be required for entry of this paper.

Favorable action on this amendment is courteously solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Daniel Swirsky', with a stylized, cursive script.

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